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09/726,499	11/30/2000	Patrick Schauerte	7040-12	1106

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EXAMINER

BRADFORD, RODERICK D

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/726,499

Applicant(s)

SCHAUERTE, PATRICK

Examiner

Roderick Bradford

Art Unit

3762

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 30 November 2000.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description:
  - 5a. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 1.7 and 2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear how the "induction unit" works.

5. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 1, "and/or" is vague because it is unclear of the scope of the claim. "Which can be" is vague because it fails to particularly point out and is unclear if this is a positive limitation of the device. "Fixed in a blood vessel of the body" is vague because applicant cannot claim positive connection to the body. It is suggested to use "adapted to be". "By way of" is vague because it fails to particularly point out. "Electrical or magnetic pulses" are inferentially included and needs to be positively recited and is vague since no structure has been set forth for producing "electrical or magnetic pulses". "Can be" is vague because it is unclear if this is a positive limitation. "A metallic, electrically conductive, tubular wire unit" is inferentially included and needs to be positively recited. "Forms" is vague because it is unclear what element "forms" the body. "Corresponding vessel and bears against...the interior" is vague because applicant cannot claim positive connection to the body. It is suggested to use "adapted to be".

Referring to claim 2, "which" is vague because it is unclear what element is being discussed.

Referring to claim 3, "itself" is vague because it fails to particularly point out.

Referring to claim 4, "acts as a unipolar stimulation pole" is vague because it is unclear what if this is functional recitation or a positive recitation.

Claims 7 and 16 are incomplete, needs induction coil. "An induction unit" is inferentially included and should positively recite element first, such as "further comprising an induction coil...".

Referring to claim 9, "characterized in that" is not of proper transitional phrase. It is suggested to use "wherein".

Referring to claim 13, "control unit" is inferentially included and needs to be positively recited.

Referring to claims 14 and 15, "pneumatically and hydraulically inflatable" is vague since no element has been set forth to inflate the balloon. It is suggested to use "adapted to be".

#### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1, 2 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehra et al. U.S. Patent No. 5,170,802.

Referring to claim 1, Mehra discloses an electrode for intravascular stimulation, cardioversion and/or defibrillation comprising:

- A stimulation probe which can be fixed in a blood vessel by way of electrical or magnetic pulses and cardioversion/defibrillation shocks can be delivered (column 2, lines 52-57)
- Wherein a metallic, electrically conductive tubular wire unit adjoins the feed line in the axial direction (16 and column 5, lines 1-3)
- Forms an expansion body that can be deployed in the corresponding vessel and bears against the wall of the vessel from the interior thereof under expansion (column 2, lines 9-13).

Referring to claim 2, wherein the inflatable balloon body is provided for expansion in the interior wire, which is plastically deformable (abstract).

8. Claims 1, 3, 8, 9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahl et al. U.S. Patent No. 5,531,779.

Referring to claim 1, Dahl discloses an electrode for intravascular stimulation, cardioversion and/or defibrillation comprising:

- A stimulation probe which can be fixed in a blood vessel by way of electrical or magnetic pulses and cardioversion/defibrillation shocks can be delivered (column 2, lines 3-7)

- Wherein a metallic, electrically conductive tubular wire unit adjoins the feed line in the axial direction (column 2, lines 42-45)
- Forms an expansion body that can be deployed in the corresponding vessel and bears against the wall of the vessel from the interior thereof under expansion (column 3, lines 46-52).

Referring to claim 3, wherein the wire unit resiliently expands itself from a pre-stressed compressed condition inside the vessel (column 4, line 6-10).

Referring to claim 8, wherein a radial diameter of the wire unit changes in the longitudinal direction (Fig. 3).

Referring to claim 9, wherein the wire unit is of a conical type (column 4, lines 3-10).

Referring to claim 13, wherein a control unit is electrically communicated to the wire unit provides at least one control signal thereto (column 2, lines 20-29).

9. Claims 1, 4, 5, 8, 12 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Macheck et al. U.S. Patent No. 5,954,761.

Referring to claim 1, Macheck discloses an electrode for intravascular stimulation, cardioversion and/or defibrillation comprising:

- A stimulation probe which can be fixed in a blood vessel by way of electrical or magnetic pulses and cardioversion/defibrillation shocks can be delivered (column 2, lines 3-7)
- Wherein a metallic, electrically conductive tubular wire unit adjoins the feed line in the axial direction (column 2, lines 42-45)

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- Forms an expansion body that can be deployed in the corresponding vessel and bears against the wall of the vessel from the interior thereof under expansion (column 3, lines 46-52).

Referring to claim 4, wherein the entire wire unit acts as a unipolar stimulation pole (column 4, lines 18-25 and column 7, lines 10,11).

Referring to claim 5, wherein the wire unit is a cylindrical coil (column 7, lines 8-10).

Referring to claim 12, wherein a further portion of the feed line extends in the axial direction parallel at least to a portion of the wire unit, such portion is electrically insulated relationship therewith (column 4, lines 18-21).

10. Claims 1, 3, 4, 15 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Spreigl et al. U.S. Patent No. 6,161,029.

Referring to claim 1, Spreigl discloses an electrode for intravascular stimulation, cardioversion and/or defibrillation comprising:

- A stimulation probe which can be fixed in a blood vessel by way of electrical or magnetic pulses and cardioversion/defibrillation shocks can be delivered (column 5, lines 12-17)
- Wherein a metallic, electrically conductive tubular wire unit adjoins the feed line in the axial direction (column 5, lines 18-17)
- Forms an expansion body that can be deployed in the corresponding vessel and bears against the wall of the vessel from the interior thereof under expansion (column 5, lines 5-10).

Referring to claim 3, wherein the wire unit expands itself from a pre-stressed position (column 5, lines 60-64).

Referring to claims 4 and 18, wherein the surface of the wire unit acts as a unipolar stimulation pole (column 7, lines 50-54).

Referring to claim 15, wherein the balloon body is hydraulically inflatable (column 11, lines 40-44).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 7, 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macheck et al. U.S. Patent No. 5,954,761 in view of Laufer et al. U.S. Patent No. 6,283,989.

Referring to claims 7, 11 and 16, Macheck fails to disclose a device wherein an induction unit supplies the electrode with voltage and inductively heats the electrode. However, Laufer discloses a device wherein an induction unit supplies the electrode with voltage and inductively heats the electrode (column 2, lines 32-37) as a means to more efficiently provide energy to the electrode.

It would have been obvious to one having ordinary skill in the art to modify the teachings of Macheck to include wherein an induction unit supplies the electrode with

voltage and inductively heats the electrode, as taught by Laufer, as a means to more efficiently provide energy to the electrode.

13. Claims 10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra (or Dahl or Macheck or Spreigl) et al. U.S. Patent No. 5,170,802.

Referring to claims 10 and 17, Mehra (or Dahl or Macheck or Spreigl) discloses the claimed

invention except for wherein the wire unit is coated with a medicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the wire unit as taught by Mehra (or Dahl or Macheck or Spreigl), with medicant since it is well known in the art that leads include a medicant to help reduce the stress on blood vessels caused by the insertion of the lead.

14. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra et al. U.S. Patent No. 5,170,802.

Referring to claims 14 and 15, Mehra discloses the claimed invention except for wherein the balloon body is pneumatically or hydraulically inflatable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Mehra, to include a balloon body that is pneumatically or hydraulically inflatable since it was known in the art that these two procedures are used as alternative means to inflate the balloon body.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*R. Bradford*

R.B. 12/02/02  
December 2, 2002

*GEORGE R. EVANISKO*  
PRIMARY EXAMINER

*12/2/02*